REMARKS/ARGUMENTS

After entry of this amendment, claims 1-11 are pending in this application, new claim 11 having been added. Claims 1, 2 and 8 are herein amended. Support for the amendment to claim 1 is provided in the specification and in original claim 2. In particular, support for "purified or synthesized" is provided in the specification, *e.g.*, at page 9, lines 29-34. Support for "18 carbon atoms" is provided in the specification, *e.g.*, at page 6, lines 16-21, and in original claim 2. Support for the addition of "a pharmaceutically acceptable carrier" is provided in the specification, *e.g.*, at Examples 6 to 10, describing the use of PBS as a carrier. Claim 2 has been amended to be in accordance with the amendment to claim 1. The amendment to claim 8, replacing "antigens" with "antigen" is merely to correct a grammatical error. Support for new dependent claim 11 is provided in the specification, e.g., at page 6, lines 6-15. No new matter is added by the amendments to claims 1, 2 and 8, and the addition of new claim 11.

Amendments to Claims 1 and 2 and Addition of New Claim 11

Applicants amended claim 1 to recite an adjuvant comprising a "purified or synthesized" hydroxy unsaturated fatty acid with "18 carbon atoms" or a derivative thereof and a "pharmaceutically acceptable carrier". The amended claim 1 is supported by the specification as described above, and by original claim 2, which has been amended to be in accordance with amended claim.

Applicants added new claim 11, which is dependent on claim 5, to recite the vaccine preparation, wherein the adjuvant constituent and antigen constituent are mixed together. New claim 11 is supported by the specification as described above.

Restriction Requirement

In accordance with 37 C.F.R. § 1.499, Applicants elect the invention of Group I with traverse. Applicants reserve the right, under 35 U.S.C. § 120, to pursue the non-elected inventions of Groups II and III in separate divisional patent applications.

The Examiner has required restriction of the instant application to one of three inventions (Groups I-III) under 35 U.S.C. § 121 and 372. In particular, the invention of Group I (claims 1-4) is drawn to an adjuvant comprising hydroxyl unsaturated fatty acid; the invention of Group II (claims 5-8) is drawn to vaccine preparations; and the invention of Group III (claims 9 and 10) is drawn to methods of administering vaccine preparations. Applicants respectfully submit that the Examiner has misapplied the test for unity of invention under 37 C.F.R. § 1.475 and request that the Examiner modify the restriction accordingly.

(A) Restriction Including Dependent Claims

37 CFR 1.475(a) states that "the requirement of unity of invention shall be fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding "special technical features". The expression "special technical features" is defined as those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art". Herein, the Examiner has used the appropriate unity of invention test, but has applied the test incorrectly. Specifically, the administrative instructions regarding the unity of invention test provide that unity of invention should be considered only in relation to the independent claims. Quoting from the MPEP, Appendix AI, Annex B, Part 1(c):

"Unity of invention has to be considered in the first place *only in relation to the independent claims* in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.). (i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, *no problem of lack of unity arises* in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention." [Emphasis added]

In this context, a dependent claim is defined as a claim which contains all the features of another claim and is in the same category of invention as that other claim (*i.e.*, product, process, use or apparatus or means, etc.), Under this definition, the following claims are "independent" ("dependent" claims therefrom are shown in parentheses):

- claim 1 (claims 2-8 and 11); and
- claim 9 (claim 10).

So long as these "independent" claims avoid the prior art (and the Examiner has made no suggestion to the contrary), and satisfy the unity of invention, there is no problem of lack of unity in respect to any claims that depend therefrom. In particular, it does not matter if a dependent claim itself contains a further invention.

In addition, regarding claims 1 and 5, the Examiner's attention is drawn to the MPEP, Appendix AI, Annex B, Part 2(II), Example 15, which states:
Claim 1: Compound A.
Claim 2: An insecticide composition comprising compound A and a carrier.
Unity *exists* between claims 1 and 2. The special technical feature common to all the claims is compound A." [Emphasis added]

In the present case, the adjuvant of claim 1 corresponds to "compound A" of exemplary claim 1, and the vaccine preparation of claim 5, comprising the adjuvant of claim 1, correspond to "an insecticide composition" of exemplary claim 2. As such, unity exists between claims 1 and 5 because the special technical feature common to these claims is the adjuvant of claim 1. In light of the above, Applicants submit that the adjuvant of the invention of Group I and the vaccine preparation of the invention of Group II should be examined in the same application.

(B) Special Technical Features Shared by the Independent Claims

After defining the independent claims for which unity of invention has to be considered, the test for unity of invention is *"whether the claims share the same or corresponding*

special technical features". In this case, the adjuvant of claim 1 is the special technical feature that distinguishes the invention from the prior art. This feature is shared by claim 9 of the invention of Group III, which is a method of administering the adjuvant of claim 1. Therefore, all of the pending claims relate to a single general inventive concept under PCT Rule 13.1 and should be examined as a single group. Applicants respectfully request that the Examiner reconsider the restriction in light of the foregoing arguments, and examine all claims in this application.

Even if the restriction is maintained, Applicants reserve the right to have the process claims (*i.e.*, the invention of Group III) rejoined with the product claims (*i.e.*, the inventions of Group I or Group II). In particular, the Examiner states that "process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance".

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

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